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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,548	12/22/2006	Anders Carlsson	4528-0124PUS2	8478
2292 7590 12/23/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER DANG, IAN D				
ART UNIT 1647		PAPER NUMBER		
NOTIFICATION DATE 12/23/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/590,548

Applicant(s)

CARLSSON ET AL.

Examiner

IAN DANG

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19, 20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16, 19, 20, 22 and 23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 18 September 2008 has been entered in full. Claims 17, 18, and 21 have been cancelled and claims 1, 13, 14, 16, and 19 have been amended.

Claims 1-16, 19-20, 22, and 23 are pending.

Election/Restrictions

Applicant's election with traverse of Group XXXVIII, claims 19-21, in the reply filed on 06/03/2008 is acknowledged. In addition, Applicant has elected wound healing as a species of diseases.

However, upon the claim amendments and the newly added claims filed 06/03/2008 and 09/18/2008, a new restriction is being made. In addition, the species election made in the reply 06/03/2008 has been withdrawn, since the restriction requirement mailed 04/03/2008 does not include a species election.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 15 and 19, as drawn to medicament comprising a peptide lipid composition comprising a peptide lipid complex in an aqueous solution.

Group II, claim(s) 15, 16, and 19, as drawn to medicament comprising a complex between LL-37 and a bilayer-forming galactolipid material.

Group III, claim(s) 2-14, 20, and 22 drawn to a method of treating infections, wound healing or other diseases with a deficiency in antimicrobial activity comprising treating a patient with a composition comprising a peptide-lipid complex in an aqueous solution.

Group IV, claim(s) 2-14, 20, 23 drawn to a method of treating infections, wound healing or other diseases with a deficiency in antimicrobial activity comprising treating a patient with a composition comprising a complex between LL-37 and a bilayer-forming galactolipid material.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-IV do not relate to a single general inventive concept because they lack the same or corresponding technical feature.

Claim 1 is directed to a peptide-lipid complex in an aqueous solution, characterized in that the lipid is a bilayer-forming galactolipid material and that the weight ratio between the peptide and the galactolipid material is 1:5-1:50. Engstrom et al. (US Patent 5,151,272; published September 29, 1992; cited as reference AA in the IDS filed 12/13/2006) teach a composition comprising the peptide insulin (column 9, claim 16) and a lipid bilayer that has galactolipid material (column 9, claim 11) characterized by about 95% to 50% by weight (column 9, claim 18) corresponding to ratios of 1:2 to 1:20. The prior art meets the limitations disclosed in claim 1. Thus Group I lacks novelty or inventive step and does not make a contribution over

the prior art. Since the first claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed invention.

Under PCR Rule 13.1, the application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

In addition, If applicant elects Group III or IV, Applicant is advised to elect one disease from infections, wound healing, or other diseases with a deficiency in antimicrobial activity. According to PCT Rule 13.2 unity of invention, only exists for diseases if they have a common pathology. Without identification of any common pathology to all of the diseases of the genus, then no special technical feature exists.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If applicant elects Group III, Applicant is required to one of the species of peptide as follows:

- a) Insulin
- b) Glucagon

- c) Erythropoietin
- d) Darbepoietin
- e) Streptokinase
- f) Somatropin
- g) Desmopressin
- h) Oxytocin
- i) Gonadorelin
- j) Nafarelin
- k) Octreotid
- l) Lanreotid
- m) Ganirelix
- n) Cetrorelix
- o) Teriparalid
- p) Salmon calcitonin
- q) Magainin 2
- r) Cecropin
- s) histatin
- t) LL-25 (SEQ ID NO:13)
- u) LL-26 (SEQ ID NO:12)
- v) LL-27 (SEQ ID NO:11)
- w) LL-28 (SEQ ID NO:10)
- x) LL-29 (SEQ ID NO:9)
- y) LL-30 (SEQ ID NO:8)
- z) LL-31 (SEQ ID NO:7)

- aa) LL-32 (SEQ ID NO:6)
- bb) LL-33 (SEQ ID NO:5)
- cc) LL-34 (SEQ ID NO:4)
- dd) LL-35 (SEQ ID NO:3)
- ee) LL-36 (SEQ ID NO:2)
- ff) LL-38 (SEQ ID NO:14)

The claims are deemed to correspond to the species listed above in the following manner: claims 9, 10, and 13.

The following claim(s) are generic: claims 20 and 22.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the peptides listed in claims 9, 10, and 13 do not share common structural and biological features.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
December 18, 2008

/Robert Landsman/
Primary Examiner, Art Unit 1647